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FOR: JONATHAN WOODSON, M.D., ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

SUBJECT: Combat Ready Clamp™ Addition to the Tactical Combat Casualty Care Guidelines 2011-07

INTRODUCTION

Tactical Combat Casualty Care (TCCC) is a set of trauma care guidelines customized for use in the pre-hospital combat setting. TCCC is currently used in training for medics by all Services in the Department of Defense (DoD) and by many U.S. coalition partners.[1,2] The Committee on Tactical Combat Casualty Care (CoTCCC), a work group of the Defense Health Board (DHB) Trauma and Injury Subcommittee, performs a quarterly review of current evidence demonstrating the successes and shortcomings of the TCCC Guidelines, and considers proposed updates and revisions.[1,2]

Junctional hemorrhage sustained in the course of combat operations is recognized as a leading cause of mortality in the current conflict in Afghanistan. Tourniquets may be difficult or impossible to apply at these sites and QuikClot Combat Gauze may not always be effective at controlling the hemorrhage. The Combat Ready Clamp™ (CRoC™) (Combat Medical Systems, Fayetteville, NC) is a U.S. Food and Drug Administration (FDA)-approved medical device indicated for the control of hemorrhage in the inguinal area that is not amenable to the application of a tourniquet.[3]

The CoTCCC began reviewing the data supporting the use of the CRoC™ in November 2010. On August 2, 2011, the CoTCCC approved the proposed addition of the CRoC™ for hemorrhage control to the TCCC Guidelines. This recommendation was approved by the DHB Trauma and Injury Subcommittee on August 3, 2011 and subsequently approved by unanimous vote of the DHB, on August 8, 2011.

BACKGROUND

On November 16, 2010 a briefing pertaining to the CRoC™ was provided to the CoTCCC, by Dr. Mel Otten, Professor of Emergency Medicine, and Director, Division of Toxicology, University of Cincinnati College of Medicine. The Work Group decided to review future field test results for potential inclusion in the TCCC Guidelines at a later date.[4]

On February 8, 2011, a representative of the Combat Development Directorate, U.S. Army Special Operations Command (USASOC), briefed the CoTCCC regarding current medical research and development projects within USASOC. He noted that the CRoC™

was being deployed by Special Operations Forces and U.S. Army Ranger units for combat evaluation.[5]

It was recommended to the CoTCCC that the CRoC™ be added to the hemorrhage control portion of the TCCC Guidelines on April 6, 2011. On August 2, 2011, the CoTCCC approved the proposed addition of the CRoC™ for hemorrhage control to the TCCC Guidelines. The DHB Trauma and Injury Subcommittee approved the recommendation on August 3, 2011. Subsequently, the DHB approved the recommendation by unanimous vote in an open session held on August 8, 2011.

DISCUSSION

Hemorrhage is the leading cause of mortality among combat casualties with potentially survivable injuries (current data indicates between 80 and 85 percent).[6, 7, 8] Of these fatalities, approximately 20 percent were due to junctional hemorrhage (neck, groin, or axillary areas).[6, 8]

A recent increase in dismounted complex blast injury (DCBI) among casualties sustained by improvised explosive devices (IED) has been noted by the Task Force on DCBI, appointed by the U.S. Army Surgeon General.[9] Additionally, significant increases in genital and genitourinary (GU) injuries have been noted.[9, 10, 11] Casualties who sustain DCBI often have proximal amputations of the lower extremities, resulting in life threatening junctional hemorrhage.[10, 12]

QuickClot Combat Gauze™ is currently the only CoTCCC-endorsed intervention for bleeding in areas not amenable to a tourniquet.[13] Research and anecdotal evidence suggest that Combat Gauze™ is safe and effective; however, it may not always control hemorrhage in junctional areas (to include the groin proximal to inguinal ligament, buttocks, gluteal and pelvic areas, perineum, axilla and shoulder girdle, and base of the neck).[4, 11, 14, 15, 16] Presently, there are no widely fielded, CoTCCC- approved devices to address severe junctional hemorrhage that are not amenable to Combat Gauze™ or a tourniquet.[4, 12]

The DHB recently recommended that DoD include studies to document the efficacy of truncal tourniquets and the ability of users to apply them effectively as a battlefield trauma care research, development, test and evaluation (RDT&E) project.[17] In anticipation of this recommendation, the United States Army Medical Research and Materiel Command (USAMRMC) posted a Request for Information (RFI) for devices that could potentially stop bleeding at compressible sites where standard tourniquets cannot be applied.[18] In this RFI, USAMRMC specified the following device design requirements:[18]

a. Ability to occlude deep bleeding from intracavitary hemorrhage, including parenchymal injuries
b. Easy application in a tactical environment with a minimum level of familiarization

c. Must not slip when tightened or following application
d. Capability of easy release and re-application
e. Be light weight
f. Have a long shelf life, low cost, and low cube

Of the limited number of candidate devices evaluated, only the CRoC™ is approved by the FDA.[11] It was approved by the FDA in August 2010 with an indication for controlling hemorrhage in the inguinal region where standard tourniquets cannot be applied and other hemorrhage control methods have been unsuccessful.[3] The FDA device description indicates that the CRoC™ may control a difficult hemorrhage for up to four hours until the casualty is able to be evacuated to a facility that can provide more definitive treatment.[3]

Specifically, the CRoC™ is applied to occlude the external iliac artery by the application of direct pressure over a packed inguinal injury site using the pressure point midway between the anterior superior iliac spine and the pubic tubercle.[19] The CRoC™ is not approved by the FDA for use in wounds to the head, neck, abdomen, or chest.

The CRoC™ also meets the other requirements as specified by USAMRMC. It is lightweight (1.5 pounds (lbs)), collapsible, and has a small cube, facilitating incorporation into a medic's aid bag.[19] The manufacturer claims and anecdotal reports support that the CRoC™ is easy to apply and remove in a tactical environment, and will not slip during tightening or after application.[19] The manufacturer also claims that the device may be adjusted to fit most patients. By design, the CRoC™is durable and has a long shelf life.[20] The CRoC™ is currently available for purchase for $445.[20]

Data from a study on normal volunteers found compression of the aortic and common iliac arteries effective in eliminating blood flow to distal extremities. The study noted that it may require up to 120 lbs to effectively do so. Of note, the study used weights to compress the artery and did not use any approved device such as the CROC [11, 21] The CRoC is capable of producing the 120 lbs of pressure needed to occlude a common iliac artery,[21] thereby eliminating the need for manual pressure, and allowing medics to attend to other casualties.[3,20]

Due to the nature of the device, pre-testing according to the indicated use is not possible.[11, 19] However, there is cadaver data supporting its use for junctional inguinal hemorrhage.[22]

A human hemostatic testing model developed at Wake Forest University School of Medicine was used to test the feasibility of the CRoC™ in stopping arterial flow when applied to the external iliac artery at or above the inguinal ligament. The study involved three trials, each including two unembalmed fresh cadaver models (175 lb, 60 year-old male and 110 lb, 70 year-old female). Blood simulant was introduced in the cadavers via a peristaltic pump. The dynamic flow rate was measured at the popliteal artery prior to and following CRoC™ application. End points were changes in arterial flow rates and alterations in arterial pressure before, during and after the application of the CRoC™ to

the external iliac artery The CRoC™ completely stopped arterial flow and pressure through the external iliac artery following four to nine turns of the device in three trials involving both cadavers.[22]

At present, the device has been fielded among the following U.S. Special Operations Forces: [19]

a. U.S. Army Special Missions Unit

b. U.S. Army 75th Ranger Regiment

In addition, the CRoC™ has been deployed on Life Flight®, the critical care air medical transport service based at Memorial Hermann Hospital in Houston, Texas.

As with any medical device, adequate training must be ensured. Medics may be trained on proper application of the CRoC™ through bleeding simulators or through repeated practice in applying it on fellow Service members.[19]

The CoTCCC identified a number of potential issues with the CRoC™:[19] It is unknown whether the device will remain stable during transport and if it may exacerbate a preexisting pelvic fracture. However, anecdotal reports from combat medics suggest that the device is very stable during transport and may enhance the stability of wound packing and dressings. Some of the CoTCCC members felt that the device may also serve to stabilize preexisting pelvic fractures. Once clarified, this will be an important component of subsequent training. An additional concern is clinical decision-making regarding the right time and place to apply the device. Of note, this last concern is not unique to the CRoC™; rather, it is an issue for all TCCC guidelines, which may be addressed through adequate training.

RECOMMENDATIONS

The Board recommends DoD incorporate the following addition to the TCCC Tactical Field Care Guidelines regarding bleeding: (proposed additions are italicized within the excerpt below):

CoTCCC guidelines amended to read:

Tactical Field Care Guidelines

4. Bleeding

a. Assess for unrecognized hemorrhage and control all sources of bleeding. If not already done, use a CoTCCC-recommended tourniquet to control life-threatening external hemorrhage that is anatomically amenable to tourniquet application or for any traumatic amputation. Apply directly to the skin 2-3 inches above wound.

b. **For compressible hemorrhage not amenable to tourniquet use or as an adjunct to tourniquet removal (if evacuation time is anticipated to be longer than two hours), use Combat Gauze as the hemostatic agent of choice. Combat Gauze should be applied with at least 3 minutes of direct pressure. Before releasing any tourniquet on a casualty who has been resuscitated for hemorrhagic shock, ensure a positive response to resuscitation efforts (i.e., a peripheral pulse normal in character and normal mentation if there is no traumatic brain injury (TBI).** ***If a lower extremity wound is not amenable to tourniquet application and cannot be controlled by hemostatics/dressings, consider immediate application of mechanical direct pressure including CoTCCC-recommended devices such as the Combat Ready Clamp™ (CRoC).***

The above recommendations were unanimously approved.

FOR THE DEFENSE HEALTH BOARD:

Nancy W. Dickey, M.D.
DHB President

Donald Jenkins, M.D.
Chair, Trauma and Injury Subcommittee

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